Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

ACK Natural, LLC
17 Spearhead Drive
Nantucket, MA
MTC 1627-C/P/R; MC281850,
MP281557; MR282038

Case No. ENF-2021-0000001126

QUARANTINE ORDER
G. L. c. 94G, §§ 4(a)(xi) and (xix),
935 CMR 500.340: Quarantine Order, and
935 CMR 501.340: Quarantine Order

Pursuant to its authority under G. L. c. 94G, §§ 4(a)(xi) and (xix), 935 Code Mass. Regs. § 500.340: *Quarantine Order*, and 935 CMR Code Mass. Regs. § 501.340: *Quarantine Order*, the Commonwealth of Massachusetts Cannabis Control Commission (the "Commission"), acting through its Executive Director, now issues this Quarantine Order requiring licensee ACK Natural, LLC (the "Respondent") to restrict the sale or use of all Marijuana and Marijuana Products it has cultivated, produced, or possessed since March 11, 2021 (collectively, the "quarantined products") having determined that Respondent's products pose an immediate or serious threat to the public health, safety, or welfare.

This Quarantine Order shall be effective upon Respondent and shall take effect on October 19, 2021, at 12:00 A.M. (the "Effective Date").

A. Factual Findings

In making its determination, the Commission finds as follows:

1. Respondent is a Colocated Marijuana Operation located at 17 Spearhead Drive on the island of Nantucket, Massachusetts. Respondent performs all cultivation and manufacturing under its medical-use license, and dispenses Marijuana and Marijuana Products under both its medical and adult-use licenses.

2. Respondent received a provisional license to cultivate, manufacture, and sell medical-use Marijuana and Marijuana Products on October 10, 2019. Respondent received its final license on March 11, 2021, and commenced adult and medical-use operations on or around July 20, 2021.

3. On January 14, 2021, Respondent received a provisional license to cultivate, manufacture, and sell adult-use Marijuana and Marijuana Products. Respondent received its final adult-use license on May 13, 2021.

4. In general, no Marijuana or Marijuana Product may be sold that is not capable of being tested by a Commission-licensed Independent Testing Laboratory ("ITL") in accordance with the Commission's *Protocol for the Sampling and Analysis of Finished Marijuana Products and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers, and Colocated Marijuana Operations* (the "testing protocol"). All ITLs are located on the mainland of Massachusetts.

5. Due to its location on the island of Nantucket and inability to fully comply with Commission regulations due to operation of law, the Commission does not require Respondent to utilize ITLs for the sampling and analysis of its Marijuana and Marijuana Products.

6. Despite its island location, Respondent must test its products in a manner that adequately protects the public health, safety, and welfare. All Marijuana and Marijuana Products must be tested for their Cannabinoid Profile and certain contaminants of concern, as specified by the Commission. The Commission has specified that licensees, including Respondent, must test all Marijuana and Marijuana Products for Mycotoxins.

7. Commission regulations permit Respondent to satisfy its testing obligations by utilizing a modified onsite testing system, provided that the testing system is approved by the Commission and uses product labels disclosing the following, "WARNING: LIMITED TESTING FOR CONTAMINANTS AND PESTICIDES."

8. In connection with its applications for licensure, Respondent adopted a modified onsite testing system (the "modified testing system"). The modified testing system is comprised of two testing-related protocols: (1) a protocol for screening Respondent's products for contaminants of concern, including Mycotoxins (the "contaminant protocol"); and (2) a protocol specific to Respondent's vaporizer products. The contaminant protocol initially submitted by Respondent included Standard Operating Procedures (the "SOPs") detailing its procedure for testing contaminants.

9. On or around January 16, 2021, Respondent submitted its initial contaminant protocol to Commission Enforcement staff for review. At that time, Respondent represented that it would utilize a dish and incubator method identifying the Hardy Diagnostic Pathogen system for the testing of Mycotoxins, that it would not sell or market product that is not capable of being tested, and that production batches to be dispensed as finished product would be tested for Mycotoxins.

10. After receiving its provisional adult-use license, Enforcement staff conducted a virtual inspection of Respondent's onsite testing laboratory on April 15, 2021. During that process, Enforcement staff spoke with the following individuals: Mike Sullivan ("Sullivan"), Quality Control Manager and Chief Executive Officer; Doug Leighton

("Leighton"), Quality Assurance Manager and Chief Financial Officer; and Tom Montgomery ("Montgomery"), Laboratory Technician.

11. During the virtual inspection, Respondent represented that Sullivan would guide laboratory operations, Leighton would maintain quality assurance records, and Montgomery would oversee the microbiological, mycotoxin, and cannabinoid profile analysis. Respondent further represented that Montgomery would also receive and process samples, maintain lab equipment, and complete data reports.

12. During the virtual inspection, Respondent again represented that it would utilize the Hardy Diagnostic Pathogen Detection System to test samples of Marijuana and Marijuana Product for Mycotoxins.

13. Enforcement staff approved the modified testing system subject to additional inspection prior to commence operations and recommended Respondent for final adult-use licensure at the Commission public meeting in May 2021.

14. After receiving final adult-use licensure, Enforcement staff conducted an onsite inspection of Respondent's facility on June 15, 2021, to conduct a post-final license inspection. Enforcement staff inspected Respondent's laboratory and observed multiple deficiencies including Respondent's failure to keep a pipette calibration log to record its laboratory practices. Enforcement staff issued a Notice of Deficiency ("NOD") dated June 17, 2021. On June 28, Respondent submitted a Plan of Correction ("POC") which agreed to use a pipette calibration log and engage the serves of an ITL, Proverde Laboratories, as a consultant on retainer.

15. On or around July 1, 2021, during a review of Certificates of Analysis ("COAs") pertaining to Respondent's Marijuana testing laboratory results, Commission Investigations Manager Tim Barwise ("Barwise") discovered that no Mycotoxin tests were reported. Upon review of Respondent's SOPs, Barwise determined that references to Mycotoxin testing procedures were missing. Barwise notified Respondent by email of the need to test its products for Mycotoxins consistent with the contaminant testing protocol. Barwise asked the Respondent to amend its SOPs accordingly.

16. On July 2, 2021, Respondent replied to Barwise's email identifying its new Mycotoxin testing equipment, TotalTox Quickscan II device ("Quickscan II"). Respondent stated that they would begin using that equipment to test products for Mycotoxins. The Respondent provided Barwise with amended SOPs. Barwise responded by confirming review of the amended SOPs, but directed that further revision was necessary to specify what equipment and test kits would be used in Respondent's Mycotoxin testing.

17. On July 3, 2021, Respondent emailed Barwise with amended SOPs including testing procedures for Mycotoxins, along with photographs of the equipment.

18. The Mycotoxins SOP submitted by Respondent on July 3, 2021, stated that Respondent would test for aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2 and ochratoxin-A (the "Mycotoxin SOP"). The Mycotoxin SOP stated the testing agent would prepare a sample and place it in the QuickScan II device and click "read test." It stated that the results would appear on screen and the testing agent would then report results in the COA. The SOP further stated the testing agent would click the "save report" button on the Quickscan II device to save a PDF version of the results. The testing agent would then click the "print report" button to create an immediate hard copy of the test results, if required.

19. On September 23, 2021, Barwise and Commission Compliance Officer Monica Pancare ("Pancare") conducted an unannounced inspection of Respondent's facility.

20. At the unannounced inspection, Barwise and Pancare interviewed Montgomery, who is responsible for testing all Respondent's products for microbials and Mycotoxins. Montgomery told Barwise and Pancare that he does not test all samples of Respondent's Marijuana or Marijuana Products for Mycotoxins. Montgomery further stated that he does not generate internal reports or logs of test results for Quality Assurance/Control purposes. As a result, Respondent's staff was unable to produce any logs, instrumentation records, or Quality Assurance reports to indicate when Mycotoxin testing was or was not performed.

21. Prior to the unannounced inspection, Respondent had sent Commission staff approximately eighty-nine (89) COAs associated with samples of its Marijuana and Marijuana Products that Respondent allegedly tested in its onsite laboratory. All COAs represented that a Mycotoxin screening had been performed and listed the results of that contaminant screening as "Test Passed."

22. On September 26, 2021, Sullivan sent an email to Barwise. In his email, Sullivan claimed that Mycotoxin screening was not originally part of Respondent's SOPs and that Respondent first learned of that requirement in June 2021. He further stated that Montgomery "incorrectly believed that a negative test for mold meant that Mycotoxins could not be present" and indicated that there had been a misunderstanding between Montgomery and Respondent's Quality Assurance/Quality Control staff regarding what constituted a "passed" Mycotoxin test. Sullivan represented that all samples of Respondent's Marijuana and Marijuana Products had been tested for Mycotoxins to date.

23. On September 29, 2021, Enforcement staff sent Respondent an NOD identifying deficiencies relating to Respondent's modified testing system. Among the deficiencies identified was Respondent's failure to follow its Testing SOP, which states that Respondent's laboratory technician will analyze retrieved data and prepare reports for its Quality Control manager.

24. On September 29, 2021, Respondent provided the Commission with an updated Mycotoxin test report. The report showed that no analyses had been performed on the QuickScan II device between July 13, 2021, and September 24, 2021. It further indicated

Mycotoxin contamination of multiple products that Respondent had previously represented as having passed Mycotoxin screening. Respondent's report also indicated incomplete Mycotoxin analyses, contradictory Mycotoxin analyses, and omitted Mycotoxin results for products previously represented by Respondent to have passed Mycotoxin screening.

25. A Mycotoxin is a secondary metabolite of fungi that is capable of causing death or illness in humans and other animals. The testing protocol mandates that Mycotoxins shall include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A. A batch of finished plant material that fails to pass the mycotoxin testing standard of 20 parts per billion or 20 micrograms/kg cannot be dispensed or sold to a patient or consumer without first being reanalyzed and/or remediated.

26. Respondent is one of two Medical Marijuana Treatment Centers located on Nantucket. There are 136 Registered Qualifying Patients residing on the island of Nantucket as of October 15, 2021.

27. Commission regulations authorize Enforcement staff to issue an Administrative Hold when there is reasonable cause to believe that a licensee's products are noncompliant or pose a threat to the public health, safety, or welfare.

28. On October 4, 2021, the Commission issued an Administrative Hold arresting the sale, destruction, transport, or transfer of three hundred and eight-nine (389) packages of Respondent's Marijuana or Marijuana Product due to their unverifiable Mycotoxin test statuses. The Administrative Hold deemed all prior COAs associated with identified products invalid and mandated Respondent to reanalyze all products and to issue new COAs that include the values of all test results obtained and are verifiable.

29. Administrative Holds allow the Commission to hold Marijuana and Marijuana Products for a limited period of time while Enforcement staff conduct a preliminary investigation into licensee compliance or the safety of its products.

30. The findings and information stated above warrant issuance of this Quarantine Order.

31. This Quarantine Order supersedes and replaces the Administrative Hold issued on October 4, 2021.

B. Statements and Violations of Law

1. The Commission shall have all the powers necessary or convenient to carry out and effectuate its purposes including […] the power to deny an application or limit, condition, restrict, revoke or suspend a license. *See* G.L. c. 94G, § 4(a)(xi).

2. The Commission shall have all the powers necessary or convenient to carry out and effectuate its purposes including […] the power to seize and remove from a licensed

premises and impound any marijuana, equipment, supplies, documents and records obtained or possessed in violation of this chapter for the purpose of examination and inspection. *See G*.L. c. 94G, § 4(a)(xix).

3. No Marijuana or Marijuana Product shall be sold or otherwise marketed pursuant to this chapter or chapter 94I that has not first been tested […] and determined to meet the Commission's testing protocols. *See* G.L. c. 94G, § 15(2).

4. Respondent's failure to independently verify that its products were tested for Mycotoxins in accordance with its modified testing system amounts to a violation of G.L. c. 94G, § 15(2).

5. Marijuana shall be tested for the Cannabinoid Profile and for contaminants as specified by the Commission. 935 Code Mass. Regs. § 500.160(2) and 501.160(2).

6. The Commission has specified that all Marijuana and Marijuana Products must be tested for certain Mycotoxins. Respondent's inability to independently verify that its products have been screened and passed testing for Mycotoxins violates 935 Code Mass. Regs. § 500.160(2) and 501.160(2).

7. If Marijuana Establishments and/or Medical Marijuana Treatment Centers operating from locations in the island counties are prevented from utilizing Independent Testing Laboratories by operation of law, they are required to test Marijuana Products in a manner that is not Unreasonably Impracticable, but also adequately protects the public health in the opinion of the Commission. *See* 935 Code Mass. Regs. § 500.200(3) and 501.200(3).

8. Respondent violated 935 Code Mass. Regs. § 500.200(3) and 501.200(3) when it failed to test its products for Mycotoxins consistent with its contaminant protocol and Testing SOP, as evidenced by Respondent's testing records which indicate that its Quickscan II device was not utilized during the period of July 13–September 24, 2021.

9. Every Marijuana Establishment and/or Medical Marijuana Treatment Center shall have and follow a set of detailed written operating procedures. *See* 935 Code Mass. Regs. § 500.105(1) and 501.105(1).

10. Respondent's failure to follow its SOPs, including its Mycotoxin SOP, and failure to establish and maintain its testing records amounts to a violation of 935 Code Mass. Regs. § 500.105(1) and 501.105(1).

11. A Marijuana Establishment and/or Medical Marijuana Treatment Center shall maintain the results of all testing for no less than one year. *See* 935 Code Mass. Regs. § 500.160(5) and 501.160(5).

12. Respondent failure to establish and maintain its testing records and failure to produce testing logs for Enforcement staff upon inspection violated 935 Code Mass. Regs. § 500.160(5) and 501.160(5).

13. Respondent's conduct, as stated in paragraphs 3–12 immediately above, pose an immediate or serious risk to the public health, safety, or welfare.

C. Order

Based on the above factual findings and Respondent's inability to independently verify that its Marijuana and Marijuana Products have passed testing for Mycotoxins, Respondent's products pose an immediate or serious threat to the public health, safety, and welfare, and further investigation is necessary to avert the threat posed by its products.

Therefore, the Commission, acting through its Executive Director, hereby **ORDERS** Respondent to:

1. Respondent **shall** quarantine and cease the sale and distribution of the following quarantined products:

    a. Quarantined products are enclosed with this Quarantine Order and marked as Exhibit A.

    b. Respondent shall create and enter all quarantined products into a virtual quarantine room in the seed-to-sale System of Record under the name "VQR 2021 10-18." Respondent must use the same name to designate quarantined products in any secondary seed-to-sale tracking system utilized by Respondent.

    c. Respondent may continue cultivation and product manufacturing activities, up to the point of testing quarantined products for Mycotoxins.

    d. Respondent may not transfer, transport, or otherwise distribute quarantined products to any other Marijuana Establishment or Medical Marijuana Treatment Center, or sell quarantined products to patients, caregivers, or consumers, unless otherwise authorized by the Commission.

2. Respondent may request an amendment or modification to this Quarantine Order to use or sell quarantined product subject to the following conditions:

    a. Respondent shall perform full-panel re-analyses of all quarantined product, with the exception of the post-harvest media contaminant screenings for pesticides and heavy metals, as required under its modified testing system.

    b. Respondent must perform two (2) re-analyses per each sample of quarantined product to screen for Mycotoxins. Respondent must perform an

initial re-analysis for all Mycotoxins followed by a second, confirmatory analysis.

c. Respondent must re-analyze samples of all quarantined product to screen for Microbiological Contaminants, Residual Solvents (as applicable), and Cannabinoid Profile.

d. Respondent must perform all re-analyses in accordance with its modified testing system.

e. If a quarantined product was derived from an intermediate product that can no longer be analyzed in the manner required under its modified testing system, then Respondent may present credible evidence to the Commission demonstrating that the required analyses were performed as represented on the quarantined product's corresponding COA.

f. Respondent must issue new COAs for each of the quarantined products. The COAs must include the values of all test results obtained. In addition to reporting values of all results obtained through sample analysis, the COAs may also include pass/fail statements.

g. Respondent shall retain the services of an independent laboratory consultant to review and verify the accuracy of the COAs and corresponding test analyses. The Respondent shall provide the Commission with the name and qualifications of the consultant.

h. Respondent shall cooperate and allow Enforcement Staff to be present for the purposes of monitoring Respondent's re-analyses of quarantined product.

i. Respondent must submit COAs for each sample of quarantined product to the Commission. Submitted COAs must include original instrument data logs, signed test records, or logs that include the exact times and dates that Respondent initiated and completed each analysis, and the times and dates of each test result.

j. Each reissued COA must bear the signatures of two (2) registered agents who have reviewed and can attest to the veracity of the test results. The reissued COA shall also bear the signature of the independent laboratory consultant retained by Respondent.

k. For each re-tested quarantined product, Respondent shall produce signed and dated Quality Assurance/Quality Control records confirming that the steps outlined in its modified testing system and related SOPs have been followed as written.

3. Respondent **shall** issue a recall of all quarantined product with unverifiable test results that has been dispensed or sold to patients or consumers in accordance with its policies and procedures under 935 Code Mass. Regs. 500.120(12)(b), 935 Code Mass. Regs. 500.130(5)(b), 935 Code Mass. Regs. 501.120(13)(b), and 935 Code Mass. Regs. 501.130(5)(b).

4. Respondent **shall** post a copy of this Quarantine Order at all public entrances to its establishment.

5. Respondent **shall** retain an independent laboratory consultant to provide training to all laboratory staff to ensure understanding of proper testing processes and laboratory competency. The Respondent shall provide the Commission with the name of the consultant and a copy of any training materials provided.

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that this Quarantine Order shall take effect on October 19, 2021, at 12:00 A.M. Failure to comply with the above conditions may result in action against Respondent up to and including suspension and/or revocation of licensure.

Nothing herein should be construed as precluding or limiting Commission authority to take additional administrative action to protect the public health, safety, and welfare.

The Commission reserves the right to rescind or amend the order or take additional action under 935 Code Mass. Regs. 500.500 and 501.500. The order shall remain in effect until the Commission rescinds or amends the order or until such other time specified in 935 Code Mass. Regs. 500.500 and 501.500.

Respondent may request a hearing within thirty (30) calendar days after the Effective Date of this Quarantine Order by making such request by email to Commission@CCCMass.com, for it to be considered timely under 935 Code Mass. Regs. 500.500(4) and 501.500(4). Because the issuance of this Quarantine Order is necessary to investigate a substantial risk to public health, safety, and welfare, Respondent may not have a right to a hearing unless and until this Quarantine Order has remained in effect for more than twenty-one (21) calendar days without any further action by the Commission. Respondent may appear *pro se* or be represented by counsel in the administrative hearing process. The Commission may conduct pre-hearing conferences or require stipulations of law and fact.

Signed this 18th day of October 2021:

Commonwealth of Massachusetts Cannabis Control Commission

Shawn Collins
Executive Director